510(k) Summary

JUL 0 1 2005

Introduction

This summary is intended to comply with requirements of the SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Applicant

Mammendorfer Institut für Physik und Medizin GmbH
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82291 Mammendorf, Germany

510(k) Correspondent

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Date Prepared

December 30, 2004

Trade Name of Device

Tesla OxySat®

Common Name of Device

Pulse Oximeter and Sensor

Classification Name

Oximeter

510(k) Classification

21CFR§870.2700 / Class II
Product Code: DQA

Device Description and Intended Use

The Tesla OxySat® design allows examination of intensive care or sedated patients while in an MRI-scanner. The Tesla OxySat® construction, fiber optic finger probe, and additional shielding make it possible to use the device within the magnetic and RF fields of the MRI examination room. During use, the unit must be positioned in a way that the maximum field strength is not higher than 20 mT, and the distance to the magnet core is at least 1.5m.

The TeslaOxySat Pulse Oximeter is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The pulse oximeter is indicated for use with adult, pediatric, and neonatal patients.

Predicate Devices

Masimo SET® /Quartz 2500 Pulse Oximeter and Accessories (K993555)

Safety & Effectiveness

Safety Testing

The Tesla OxySat complies with the Safety Testing requirements of EN 60601-1 (IEC 601-1).

EMC Compliance

The Tesla OxySat complies with the EMC requirements of standard EN 60601-1-2.

Biocompatibility

The patient contact portions of the Tesla OxySat fiber optic finger probe comply with the biocompatibility requirements of standard ISO 10993-1.

MRI Compatibility Tests

Testing was completed to determine the influence of the Tesla OxySat on the MRI system, and the influence of the MRI system on the Tesla OxySat®.

Functional Testing

Function and accuracy of the Tesla OxySat was tested in both normal environment (Non MRI) and in MRI environment.

Equivalency Testing

Laboratory testing using human subjects was conducted to validate the functional and accuracy specifications of the pulse oximeter and sensors, and to demonstrate equivalency to the predicate device.

Risk Management

This device has been designed to either completely eliminate or mitigate known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program.

The user must be qualified in MRI and pulse oximeter procedures, and must be familiar with all labeling and instructions for use associated with the device.

Mammendorfer Institut für Physik und Medizin GmbH believes that the Tesla OxySat® is safe and effective when used as instructed by knowledgeable and trained personnel, and is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mammendorfer Institute for Physics and Medicine GMBH
C/o Mr. Robert N. Clark
Medical Device Regulatory Advisors
13605 West 7th Avenue
Golden, Colorado 80401

JUL 01 2005

Re: K050018
Trade/Device Name: Tesla OxySat®
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: May 6, 2005
Received: May 10, 2005

Dear Mr. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: _____

Device Name: *Tesla*$^{OxySat®}$

Indications for Use:

The TeslaOxySat Pulse Oximeter is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The pulse oximeter is indicated for use with adult, pediatric, and neonatal patients. The TeslaOxySat PulseOximeter is designed for use in an MRI-environment at a maximum magnetic field strength of 20mT.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050018

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

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